DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 15, 1999

Mr. Thomas E. Wheeler
President/CEO, CTIA
1250 Connecticut Ave, N.W. Suite 800
Washington, D.C. 20036

Dear Dr. Jacobson and Mr. Wheeler:

It is my understanding that a collaborative project between the parties identified below is being considered. Accordingly, until the formal Cooperative Research and Development Agreement (CRADA) is negotiated by the parties, reviewed by the CRADA Review Board, and approved by the Commissioner of the Food and Drug Administration, (FDA) this Letter is offered to permit the collaboration to begin.

It is acknowledged by the parties below that the collaboration detailed in the Research Plan, attached as Appendix A, will be conducted informally by the Center for Devices and Radiological Health (CDRH)/FDA and the Collaborator pending formal approval of the CRADA. Pursuant to its authority under the Federal Technology Transfer Act of 1986, FDA agrees that should the CRADA be approved, it will have a retroactive effect to the date that the last party executed this Letter for

1. any inventions that may result under the Research Plan;
2. any publications that may result under the Research Plan; and
3. confidentiality obligations specified in the attached Public Health Service (PHS) Model CRADA in effect as of May 27, 1999.

The Model CRADA provisions for the protection of proprietary information are incorporated by reference and are considered controlling. These provisions include, but are not limited to Articles 2.7 and 8.1-8.7. A copy of the Model CRADA is attached.

Both parties identified below understand, however, that this Letter is not a commitment on the part of either party to enter into a CRADA. Further, this Letter is effective for a term not to exceed six months from date of execution. The parties may enter an agreement to extend this term, provided a formal CRADA is under active negotiation and the collaborative research is continuing. With the necessary approvals as discussed above, we look forward to a successful and mutually beneficial collaboration.

Sincerely,

Beatrice A. Drake
Technology Development Officer, FDA

AGREED AND ACCEPTED:

Center for Devices and Radiological Health/FDA

Elizabeth D. Jacobson
Deputy Director, CDRH

10/18/99
Date

Cellular Telecommunications Industry Association (CTIA)

Thomas E. Wheeler
President/CEO. CTIA

10/18/99
Date

Appendix A: Research Plan

The following outlines the activities that will be conducted by the collaborating members of the Cooperative Research and Development Agreement. For purposes of the CRADA, the collaborating members are the U.S. Food and Drug Administration, Center for Devices and Radiological Health (CDRH) and the Cellular Telecommunications Industry Association (CTIA).

The purpose of the CRADA is to provide research recommendations, and to provide scientific oversight of research based on such recommendations, on the health effects of RF emissions from wireless phones. The scope of the research to be planned and undertaken shall address the results of certain scientific studies previously conducted by the Wireless Technology Research, L.L.C. (WTR). CDRH will provide scientific and technical advice on the studies which should be performed and, as appropriate, obtain input from government, industry and private scientific and technical experts (e.g., through meetings). CTIA will directly administer the actual research conducted by third parties pursuant to individual research contracts, based upon the recommendations made by CDRH and the scientific and technical experts. CTIA will provide support to CDRH for the activities it must undertake to carry out its role in this CRADA as agreed by the parties. When appropriate, travel expenses and honoraria for scientific and technical experts will also be provided by CTIA. The processes set forth in this CRADA are intended to ensure that the ensuing research is conducted in a way that promotes quality, scientific independence, integrity and efficiency.

For purposes of this CRADA, the research activities to be facilitated and pursued regarding health effects of RF emissions from wireless phones will focus on two areas: (1) mechanistic studies related to genotoxicity (or carcinogenesis) and (2) research or recommendations on additional epidemiologic studies, in each case as further described below. In order to avoid unnecessary duplication and in recognition of the international nature of the scientific community and of the wireless industry, any recommendations for further study will consider the scientific literature and ongoing research from an international perspective. This could be achieved through consultation with organizations around the world engaged in review and research on the health effects of RF emissions and wireless phones, such as the World Health Organization International EMF project.

The scientific activities under this agreement will be undertaken using the following general approach. CDRH will review the WTR research and related research, identify the scientific questions of merit, propose research to address these questions, propose estimated budgets, and provide detailed recommendations on the conduct of such studies.

CTIA will then issue requests for proposal (RFP) for such studies as are feasible given CTIA's available budget and will obtain proposals from third parties interested in conducting the studies. CDRH will work with CTIA to review the proposals for responsiveness to identified research needs and available budgets, and will make

recommendations on proposal selection. CDRH will work with CTIA to address budget issues raised by the research proposals. CTIA will directly administer the funding of the research, which funds will be provided through individual research contracts specifying budgets and completion dates.

Following completion of the agreed research projects, CDRH will evaluate the conduct of such research, review the results obtained, and issue a report to CTIA

It is the intent of CDRH throughout this process to obtain outside input that comprises the best available scientific and technical expertise.

A summary of the studies to be planned and conducted hereunder is set forth below:

Genotoxicity: The purpose of this portion of the research is to follow up on the findings of the previously conducted WTR studies using the micronucleus assay. Potential issues to be addressed include the accuracy and reproducibility of the WTR results, the critical parameters upon which these results depend, and exposure dosimetry.

Epidemiology: The purpose of this portion of the research is to follow up on the findings of the WTR cohort and case control studies, and to evaluate the need for participation in a multi-center case control study, such as that being coordinated by International Agency for Research on Cancer. The initial goals are to identify the type of follow up research that is warranted, and to establish the relative priority of warranted studies. Potential issues to be addressed include the type of follow up studies required to address pertinent unanswered questions, whether additional information is necessary to perform such an evaluation, and whether an additional case control study is required.